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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	**PAPER NUMBER**
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,962	HANSON ET AL.	
	Examiner	Art Unit	
	DILEK B. COBANOGLU	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/02/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,19-30 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,19-30 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/29/2001,6/4/2002,7/29/2002,5/22/2007,6/29/2007.

DETAILED ACTION

Notice to Applicant

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/2007 has been entered. Claims 16, 19-30 and 37 remain pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 37 is rejected under 35 U.S.C. 102(e) as being unpatentable by Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. As per claim 37, Brook discloses a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparing a source of a drug to be administered to a patient (Brook; col. 6, line 56 to col. 7, line 31),

ii. associating a unique tracking code with said source (Brook; col. 5, lines 48-54),

iii. providing first data associated with said tracking code relating to said drug to be administered (Brook; col. 5, lines 48-54),

iv. providing second data representing an amount of said drug administered to said patient from said source associated with said tracking code (Brook; col. 7, lines 32-50, col. 8, lines 27-65),

v. providing third data associated with disposing of said source (Brook; col. 6, lines 36-55, col. 10, line 51 to col. 11, line 12),

vi. storing said first, second and third data in association with said tracking code on a storage device (Brook; col. 6, lines 2-19),

vii. retrieving said first, second and third data from said storage device using said tracking code, whereby said first, second and third data associated with said tracking code tracks said source from said preparing of said source through administration of said drug to a patient to said disposal thereof (Brook; col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 16, 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775) in view of Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. Claim 16 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. providing a source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19),

ii. associating a unique tracking code with said source, <u>wherein said unique tracking code is unique as to a single source</u> providing data associated with said drug to be administered,

iii. storing said data in association with said tracking code on a storage device, whereby said data may be altered while still being associated with the same unique tracking code, and

iv. retrieving said data from said storage device using said tracking code, wherein said data tracks said drug and said source from providing of said source to said disposing of said source

Walker fails to expressly teach "associating a unique tracking code with said source, wherein said unique tracking code is unique as to a single source providing data associated with said drug to be administered". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "associating a unique tracking code with said source, wherein said unique tracking code is unique as to a single source providing data associated with said drug to be administered". (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

B. As per claim 19, Walker discloses the method of claim 16, wherein said tracking code comprises a bar code (Walker; col. 2, lines 29-35, col. 6, lines 25-32).

C. As per claim 20, Walker discloses the method of claim 19, further including scanning said bar code for identifying said drug associated with said bar code prior to administration of said drug to a patient (Walker; col. 6, line 66 to col. 7, line 8, col. 7, lines 49-57).

D. As per claim 21, Walker discloses the method of claim 16, further including affixing said source to a cradle (Walker; col. 6, lines 20-37).

E. As per claim 22, Walker discloses the method of claim 21, further including adhering a label containing said tracking code to at least one of said cradle and said source (Walker; col. 6, lines 20-37).

F. As per claim 23, Walker discloses the method of claim 21, wherein said cradle comprises a syringe label cradle (Walker; col. 5, lines 49-59).

G. As per claim 24, Walker discloses the method of claim 21, wherein said cradle comprises a port label cradle (Walker; col. 5, lines 49-59).

H. As per claim 25, Walker discloses the method of claim 16, wherein said source comprises a syringe (Walker; col. 5, lines 49-59).

I. As per claim 26, Walker discloses the method of claim 16, wherein said source comprises an IV port (Walker; col. 5, lines 3-9).

J. Claim 27 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparation of a source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19),

ii. affixing said source in a cradle (Walker; col. 6, lines 20-37),

iii. providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle (Walker; col. 6, lines 20-37), wherein said unique tracking code is unique as to a single source,

iv. identifying data associated with said drug and said patient (Walker; col. 1, lines 54-67, col. 2, lines 28-47),

v. storing said data in association with said unique tracking code on a storage device (Walker; col. 5, lines 26-40, col. 13-47),

vi. administering a quantity of said drug to a patient (Walker; col. 5, lines 26-40, col. 13-47),

vii. disposing of said source after administration of said drug to a patient,

viii. updating said data and said quantity of said drug administered in association with the same unique tracking code with the updated data.

- Walker fails to expressly teach "a unique tracking code is unique as to a single source". However, this feature is well known in the art, as evidenced by Brook.

  In particular, Brook discloses "a unique tracking code is unique as to a single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40).

  It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

- Walker fails to expressly teach "disposing of said source after administration of said drug to a patient, updating said data and said quantity of said drug administered in association with the same unique tracking code with the updated data". However, this feature is well known in the art, as evidenced by Brook.

  In particular, Brook discloses "disposing of said source after administration of said drug to a patient, updating said data and said quantity of said drug administered in association with the same unique tracking code with the updated data" (Brook; abstract, col. 10, line 51 to col. 11, line 12).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

K. Claims 28 and 29 repeat the same limitations as claims 25 and 26 respectively. Therefore rejected for the same reasons given above in the rejections of claims 28 and 29, and incorporated hereinwith.

L. As per claim 30, Walker discloses the method of claim 27, said tracking code identifies a single source associated with a single patient (Walker; col. 5, lines 3-9).

Response to Arguments

6. Applicant's arguments with respect to claims 16 and 27 have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER